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**MÁ OCLUSÃO E O USO DE CHUPETA ORTODÔNTICA OU  
CONVENCIONAL: UMA META-ANÁLISE**

Dissertação submetida ao  
Programa de Pós-Graduação  
da Universidade Federal de  
Santa Catarina para a  
obtenção do Grau de Mestre  
em Odontologia.

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Florianópolis  
2017

Ficha de identificação da obra elaborada pelo autor,  
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Medeiros, Raphaela  
MÁ OCLUSÃO E O USO DE CHUPETA ORTODÔNTICA OU  
CONVENCIONAL: : UMA META-ANÁLISE / Raphaela Medeiros ;  
orientador, Ricardo de Souza Vieira ; coorientador,  
Marcos Ximenes. - Florianópolis, SC, 2017.  
92 p.

Dissertação (mestrado) - Universidade Federal de Santa  
Catarina, Centro de Ciências da Saúde. Programa de Pós  
Graduação em Odontologia.

Inclui referências

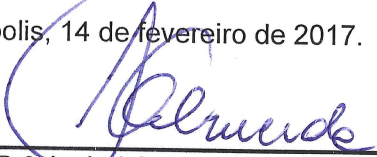
1. Odontologia. 2. Ortodontia. 3. Odontopediatria. 4.  
Má oclusão. 5. Uso de chupeta. I. de Souza Vieira, Ricardo  
. II. Ximenes, Marcos . III. Universidade Federal de Santa  
Catarina. Programa de Pós-Graduação em Odontologia. IV.  
Título.

Raphaela de Souza Medeiros'

## **MÁ OCLUSÃO E O USO DE CHUPETA ORTODÔNTICA OU CONVENCIONAL: UMA META-ANÁLISE**

Esta dissertação foi julgada adequada para obtenção do  
Título de "Mestre", aprovada em sua forma final pelo  
Programa de Pós-Graduação em Odontologia.

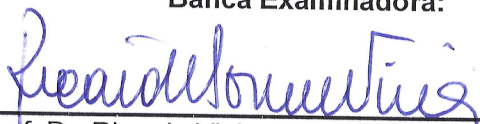
Florianópolis, 14 de fevereiro de 2017.



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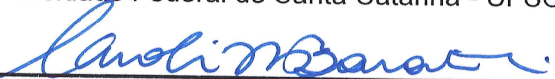
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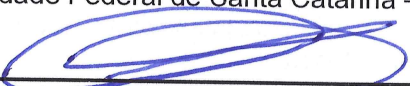
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*"Jamais desista das pessoas que ama.  
Jamais desista de ser feliz. Lute sempre pelos seus sonhos. Seja  
profundamente apaixonado pela vida. Pois a vida é um  
espetáculo imperdível."*

**Augusto Cury**



## **AGRADECIMENTOS**

À Universidade Federal de Santa Catarina e aos professores do Programa de Pós-graduação em Odontologia, em especial aos professores da área de concentração em Odontopediatria: Michele Bolan, Izabel Almeida, Joeci, Ana Paula, Mariane Cardoso e ao meu orientador Ricardo Vieira, obrigada por me acolher como orientanda e pelo apoio. À doce e tão solícita secretária do programa, Ana Maria Frondolozo.

Aos professores de Revisão Sistemática Graziela De Luca Canto e André Luís Porporatti por me darem sempre muita atenção quando precisei de uma forma tão generosa com todos os seus conhecimentos. À bibliotecária professora Maria Gorete Savi pelas diversas vezes que ajudou nas estratégias de busca. E à professora Daniela Carcereri, por me acolher com tanto carinho e respeito.

A todos os meus colegas de pós-graduação da área de odontopediatria: Nashalie, Bárbara (Ba), Fernanda, Dani, Ricardo, Angela (uma angel), Bruna, Dani Klein, Jéssica, Poliana e Josi. Obrigada por toda força e apoio em todos meus momentos.

Aos meus amigos que (re)conheci nesta jornada: Igor, Ana, Nayra e Fê, pessoas do bem, que me trouxeram luz e a benção de grandes amigos. Obrigada por estarem ao meu lado.

Ao meu co-orientador Marcos Ximenes, por me ensinar tantas coisas, por me estimular a evoluir, por estar do meu lado nesses 2 anos se dedicando ao meu aprendizado. Muito obrigada!

À minha colega de mestrado e atualmente uma grande professora, Carla Massignam, minha especial gratidão pela dedicação à este trabalho, meu enorme obrigada e profunda admiração pela pessoa que és, pela professora, pela colega de turma e pela grande mulher.

Aos meus pais, Sonia e José, que me apoiaram na minha escolha, que vibram comigo em minhas vitórias e que são meus maiores amigos. À minha irmã e sobrinhas, pela torcida, pelo apoio e pelo amor.

Ao meu namorado, Alison, que segurou em minha mão e embarcou junto comigo em busca dos nossos sonhos, obrigada pela parceria, torcida e proteção.

À minha melhor amiga, Karla, que não está neste plano, mas que tenho certeza que me benze aonde eu for. Obrigada, por ser minha maior cúmplice e meu verdadeiro símbolo da amizade.

À Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES), que me forneceu uma bolsa de estudos para a realização desta e outras pesquisas durante o mestrado.



## RESUMO

O objetivo deste estudo foi estimar a prevalência de má oclusão em usuários de chupeta ortodôntica e convencional. Foram incluídos estudos observacionais em crianças de 0-60 meses que utilizaram chupeta ortodôntica ou convencional. A pesquisa foi feita em cinco bancos de dados: *Latin American and Caribbean Health Sciences (LILACS)*, *PsycINFO*, *PubMed*, *Scopus* e *Web of Science*. Além disso, foi realizada a busca na literatura cinza por meio do Google Scholar e do banco de dados System for Information on Gray Literature in Europe (OpenGrey). As dissertações e teses foram pesquisadas por meio da base de dados de Dissertações e Teses ProQuest. Além disso, foram realizadas pesquisas manuais das listas de referência dos estudos selecionados. Foram encontrados 607 artigos nas bases de dados, dos quais 119 foram selecionados para leitura completa por dois revisores (RM e MX) e por fim, 3 estudos foram incluídos na revisão sistemática e meta-análise. Os estudos incluídos tiveram a qualidade metodológica avaliada pelo MASTARI. 57,6 % (95 % de IC 44,8 a 69,6, total = 64) dos usuários de chupeta convencional apresentaram overjet acentuado, 47,2% das crianças usuárias de chupeta ortodôntica (95 % IC 35,3 a 59,3, total = 70) e 11,4% das crianças sem o hábito (95 % IC 6,7 a 17,9; total=137). 51,6% dos usuários de chupeta convencional apresentaram mordida aberta anterior (95 % IC 15,8 a 86,5, total = 102), 40,8% dos usuários de chupeta ortodôntica (95 % IC 9,6 a 77,0, total = 152) e 3% das crianças sem o hábito (95 % IC 1,2 a 6,2; total=224). 12,7% (95 % IC 7,0 a 20,6, total = 102) dos usuários de chupeta convencional e 12,1% (IC 95 % 7,4 a 18,4, total = 152) dos usuários de chupeta ortodôntica apresentaram mordida cruzada posterior e 2,7 (95 % IC 1,0 a 5,8; total=226) das crianças sem o hábito. Existe maior prevalência de overjet acentuado e mordida aberta anterior em crianças com chupeta convencional em comparação com a ortodôntica. Entretanto não foi encontrada diferença em relação à mordida cruzada posterior. Há uma maior prevalência de má oclusão entre usuários dos dois tipos de chupetas do que em crianças sem hábito de sucção não nutritiva.

**Palavras-chave:** Má oclusão. Chupetas. Dente decíduo. Revisão.



## ABSTRACT

The aim of this study was to estimate the prevalence of malocclusion in users of orthodontic and conventional pacifier. Observational studies in children aged 0-60 months who used orthodontic or conventional pacifier were included. The search was made in five databases: Latin American and Caribbean Health Sciences (LILACS), PsycINFO, PubMed (including MedLine), Scopus and Web of Science. A partial grey literature search was taken using Google Scholar and the database System for Information on Grey Literature in Europe (OpenGrey). Dissertations and theses were searched using the ProQuest Dissertations and Theses database. In addition, hand-searching of the reference lists of selected studies were performed. A total of 607 articles were found in the databases, of which 119 were selected for complete reading by two reviewers (RM and MX) and finally, 3 studies were included in the systematic review and meta-analysis. The included studies had the methodological quality assessed by MASTARI. Users of conventional pacifier had 57.6% (95% CI 44.8 to 69.6; total=64) of accentuated overjet, orthodontic pacifier 47.2% (95% CI 35.3 to 59.3; total=70) and no habit 11.4% (95% CI 6.7 to 17.9; total=137). Anterior open bite in users of conventional pacifier was 51.6% (95% CI 15.8 to 86.5; total=102), orthodontic pacifier 40.8% (95% CI 9.6 to 77.0; total=152) and no habit 3.0% (95% CI 1.2 to 6.2; total=224). Posterior crossbite in users of conventional pacifier was 12.7% (95% CI 7.0 to 20.6; total=102), orthodontic pacifier 12.1% (95%CI 7.4 to 18.4; total=152) and no habit 2.7% (95% CI 1.0 to 5.8; total=226). There was greater prevalence of accentuated overjet and anterior open bite in children using conventional pacifier compared to orthodontic. There was no difference in posterior crossbite. There is higher prevalence of malocclusion among users of two types pacifiers than in children without sucking habit.

**Keywords:** Malocclusion. Pacifier. Review Systematic. Primary teeth.



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## **LISTA DE ABREVIATURAS E SIGLAS**

AAP – American Academy of Pediatric  
COBE- Centro Brasileiro de Pesquisas Baseadas em Evidência  
CG- Control Group  
CI- Confidence interval  
CP - Conventional Pacifier  
CC - Chupeta convencional  
OP - Orthodontic Pacifier  
CO - chupeta ortodôntica  
AO - Accentuated overjet;  
AOB - Anterior openbite;  
PCB - Posterior crossbite;  
LILACS - Latin American and Caribbean Health Sciences  
CS- Cross sectional  
High- High risk of bias  
Low- Low risk of bias  
Moderate- Moderate risk of bias  
NA- Not applicable  
NC- Not clear  
NH- No sucking habit  
NI- Not informed  
N- No  
SD- Standard deviation  
SIDS - Sudden Infant Death Syndrome  
UFSC- Universidade Federal de Santa Catarina  
Y- Yes



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## 1 CONTEXTUALIZAÇÃO

O ato de sucção se inicia já na vida intrauterina, ele é um reflexo inato da criança entendido como necessidade fisiológica (NELSON, 2012). Dentre os hábitos de sucção não nutritiva, o uso da chupeta apresenta relevante prevalência entre as crianças, é culturalmente estabelecido e socialmente aceitável (NIHI 2015).

A prevalência de uso de chupeta pode chegar a 82%, dependendo da idade e da população estudada. Nos países ocidentais varia de 75-95% (NIHI, 2015, DUNCAN, 2008, AZNAR, 2006). Na Inglaterra, aos 15 meses de idade, 37,6% das crianças são usuárias de chupeta (DUNCAN, 2008). Entretanto, a prevalência do hábito de sucção não nutritivo pode diminuir com a idade, variando de 56% aos 6 meses à 5 % aos 4 anos de idade (WARREN, 2000). Um estudo mostrou que não há diferença em relação ao hábito de chupeta entre meninos e meninas entre 1 e 8 anos de idade, sendo que até o final do primeiro ano de vida a prevalência do uso de chupeta é maior do que a de sucção digital (BISHARA, 2006).

O uso da chupeta apresenta benefícios e malefícios segundo a literatura. Dentre os benefícios, está sua capacidade de acalmar, tranquilizar e permitir autocontrole por parte do bebê (NELSON, 2012; WAGNER; HEINRICH-WELTZIEN, 2016). Além disto, a Academia Americana de Pediatria (AAP) (AAP, 2005), tem como recomendação o uso da chupeta no primeiro ano de vida da criança, particularmente no momento em que o bebê for dormir, com embasamento na literatura que demonstra sua associação positiva com a redução da Síndrome de Morte Súbita do Latente (SMSL), embora a hipótese do porquê ocorre esta relação ainda não está estabelecida (ALM et al, 2016).

Por outro lado, estudos apontam desvantagens no uso da chupeta, como a otite média aguda, possível impacto negativo na amamentação natural e um fator etiológico para o desenvolvimento de má oclusão (NELSON, 2012, ROVERS et al, 2008), devido à interferência dos movimentos fisiológicos dos músculos periorais e língua (SOUSA, 2014). Entre os usuários de chupeta, aproximadamente 27% das crianças com idades entre 2-5 anos desenvolvem algum tipo de malocclusão (NIHI, 2015). A prevalência de mordida aberta anterior varia de 17% a 96% (NIHI, 2015, LIMA, 2016), a mordida cruzada

posterior apresenta índices de 27% a 88% e a presença de overjet acentuado é diagnosticada em 52% desses indivíduos (LIMA, 2016).

A má oclusão associada ao uso da chupeta pode estar influenciada pela frequência, duração e intensidade (LIMA, 2016, MODÉER, 1982, BUENO, 2013). Observou-se que quanto maior a duração, frequência e intensidade do hábito de sucção, a chance do desenvolvimento de má oclusão aumenta (MODÉER, 1982, ABRAHÃO, 2009, BISHARA, 2006). Bishara (2006) e colaboradores, avaliando a duração do uso de chupeta em meses, observou que crianças que usaram chupeta até os 12 meses de idade apresentaram prevalência de 2,1% de mordida aberta anterior e 6,3% de mordida cruzada posterior, enquanto que as crianças que usaram por mais de 48 meses apresentaram 25% de mordida aberta anterior e 41,7% de mordida cruzada posterior. Modéer (1982) a partir da avaliação da frequência (horas) de uso, mostrou que crianças que usavam até 1 hora por dia apresentavam menor prevalência de má oclusão em relação àquelas que usavam de 6 a 15 horas por dia. Bueno (2013), mostrou que crianças que usaram chupeta por mais de 3 anos tiveram 33,3 vezes mais chance de ter mordida aberta, 2,77 de overjet acima de 5 mm e 5,26 de mordida cruzada posterior.

Comercialmente, existem tipos diferentes de chupetas classificadas de acordo com a forma anatômica (chupeta convencional e chupeta ortodôntica). A Chupeta convencional (CC) apresenta um formato de bico do tipo "cereja", ou seja, arredondado e a chupeta ortodôntica (CO) é confeccionada com o bico mais achatado com a proposta de simular a anatomia dos mamilos das mães, visando reduzir o risco de má oclusão devido ao posicionamento da língua durante o ato de mamar e selamento labial aceitável (LIMA, 2016, ZARDETTO, 2002, ADAIR, 1992).

Embora as chupetas ortodônticas sejam amplamente utilizadas e comercializadas com desenho anatômico que propõe reduzir o risco de má oclusão, há falta de estudos na literatura que comprovem a vantagem em relação à convencional. Uma metanálise publicada na literatura com dados até 2014, concluiu que não há possibilidade de afirmar a existência de diferenças quanto às consequências do uso de diferentes formas de chupetas para o sistema estomatognático (CORRÊA, 2016).

Segundo Adair (1995), o qual realizou um estudo transversal para comparar o uso das chupetas ortodônticas e convencionais em relação à má oclusão, parece não haver vantagem para a chupeta ortodôntica com relação à convencional e que a mordida aberta anterior

e a mordida cruzada posterior estão mais associadas com o tempo de uso da chupeta do que o tipo anatômico.

Em outro estudo, feito por Mesomo et al (2004), o qual avaliou crianças entre 3 e 6 anos de idade, identificou não haver vantagens nas chupetas ortodônticas e que o desenvolvimento da má oclusão estava associado ao hábito prolongado de sucção de chupeta. Além disso, seus achados mostraram que a mordida cruzada posterior foi mais presente em crianças usuárias de chupetas ortodônticas em relação às convencionais.

Com base na grande prevalência do uso de chupeta na vida diária das crianças e na comercialização de chupetas anatomicamente feitas para um menor dano à oclusão dentária, este estudo teve como objetivo atualizar a literatura por meio de uma revisão sistemática, devido à novos estudos na literatura e critérios de elegibilidade mais direcionados a responder à seguinte questão: em crianças, há diferença na prevalência da má oclusão entre o tipo de chupeta utilizado (convencional ou ortodôntico)?





## 2 OBJETIVO

### *2.1 Objetivo geral*

Estimar a prevalência de má oclusão em crianças usuárias de chupeta ortodôntica e convencional.

### *2.2 Objetivo específico*

- Avaliar se há vantagens na chupeta ortodôntica em relação à chupeta convencional com relação à proteção da má oclusão.
- Comparar crianças usuárias de chupeta, ortodôntica ou convencional, com crianças livres de hábitos de sucção não nutritiva.
- Avaliar a interferência das variáveis tempo, duração ou intensidade de uso de chupeta no desenvolvimento da má oclusão.



### 3 METODOLOGIA

Esta revisão sistemática e metanálise seguiram os itens preconizados pelos *Preferred Reporting Items for Systematic Reviews and Meta-Analysis* (PRISMA) (MOHER, 2015). Além disso, este protocolo foi concluído e registrado no *International Prospective Register of Systematic Reviews* (PROSPERO CRD42016045826) (ANEXO 1).

#### 3.1 Critérios de elegibilidade

Para serem incluídos, os artigos selecionados tiveram que atender aos seguintes critérios: estudos observacionais em crianças de 0-60 meses que usaram chupeta ortodôntica ou convencional. Todos os fatores associados ao uso da chupeta foram aceitos: qualquer avaliação de frequência, duração ou intensidade descrita nos estudos. Foram incluídos artigos publicados e não publicados, em todas as línguas, sem restrição de data.

#### 3.2 Critério de exclusão

Os critérios de exclusão seguiram a estratégia PECOS (NEEDLEMAN, 2002). O acrônimo PICO (ou PECO) auxilia na construção da questão em quatro partes: Paciente/Problema; Intervenção/Exposição; Comparação e Desfecho (MAIA, ANTONIO, 2012). Podendo ser acrescentado o tipo de estudo, componente S do acrônimo: (P - participantes) Estudos: 1) com pacientes síndrômicos genéticos (por exemplo, síndrome de Down, anomalias craniofaciais, desordens neuromusculares, etc); 2) em crianças com malignidades, desnutrição e doenças crônicas; 3) em crianças com outros hábitos de sucção não nutritivos, ou interposição lingual, ou adenoides aumentadas, ou problemas respiratórios; 4) em crianças com histórico de uso de aparelhos ortodônticos; 5) realizado em crianças com mais de 60 meses; 6) que incluía cirurgia maxilo-facial; (E - exposição): 7) que não mediram as características de uso da chupeta (frequência, duração ou intensidade); 8) em crianças que utilizaram ambos os modelos de chupetas simultaneamente (ortodôntico e convencional) ou não

diferenciam grupos por tipos de chupetas; (Comparação C): 9) sem grupo controle ativo (chupeta convencional); E (S - Tipos de Estudos) 10) referências duplicadas com a mesma amostra; 11) Resenhas, cartas, opiniões pessoais, relatos de casos, capítulos de livros e resumos de conferências; E 12) artigos não encontrados.

### *3.3 Fontes de informação e estratégias de pesquisa*

Uma pesquisa eletrônica foi realizada em 5 de maio de 2016, com atualização feita em 17 de dezembro de 2016. Foram realizadas estratégias de busca individuais e específicas para cada uma das seguintes bases de dados eletrônicas: *Latin American and Caribbean Health Sciences* (LILACS), PsycINFO, PubMed (incluindo MedLine) Scopus e Web of Science. Uma pesquisa parcial na literatura cinza foi feita usando o Google Scholar e o banco de dados *System for Information on Grey Literature in Europe* (OpenGrey). As dissertações e teses foram pesquisadas através da base de dados de Dissertações e Teses ProQuest. Além disso, foram realizadas pesquisas manuais nas listas de referência dos estudos selecionados. Os termos de pesquisa foram desenvolvidos com a ajuda de um bibliotecário experiente em ciências da saúde e foram abrangentes para incluir estudos que relatam o uso da chupeta ortodôntica ou convencional e má oclusão sob uma série de outros sinônimos (Apêndice 1). As referências foram gerenciadas pelo software de gerenciamento de referência EndNote® Basic (Thomson Reuters, Nova York, EUA) e os estudos duplicados foram removidos.

### *3.4 Seleção de estudos*

Os artigos foram selecionados em duas fases. Dois revisores (RM e MX) examinaram independentemente os títulos e resumos de todas as referências para eliminar estudos notoriamente irrelevantes na fase 1. Na fase 2, os textos completos foram revisados independentemente pelos mesmos revisores (RM e MX) e selecionados de acordo com os critérios de elegibilidade determinados. As discordâncias foram analisadas por meio de discussão e um terceiro revisor (CM) foi consultado, se necessário, para tomar uma decisão final.

### *3.5 Processo de coleta de dados*

Um revisor (RM) realizou a extração de dados e um segundo revisor (MX) verificou todas as informações apuradas, com discordância resolvida por consenso. Um terceiro autor (CM) foi envolvido, quando necessário, para tomar uma decisão final.

### *3.6 Coleta de dados*

Foram extraídos os seguintes dados: características do estudo (autor, ano, país, desenho e cenário), características da população (tamanho da amostra e idade) e características dos resultados (prevalência e principal conclusão).

### *3.7 Risco de viés em estudos individuais*

A *Meta-analysis of Statistics Assessment and Review Instrument* (MAStARI) do Instituto Joanna Briggs foi a ferramenta do risco de viés utilizada. Dois revisores (RM e MX) classificaram de forma independente a qualidade metodológica dos estudos selecionados como de alto risco de viés quando o estudo alcançou 49% de pontuação "sim", moderada de 50% a 69% pontuação "sim" e baixo para mais de 70 % "sim". As inconsistências nas classificações foram resolvidas por consenso quando possível, ou um terceiro revisor (CM) tomou a decisão final. O RevMan Software (Review Manager, versão 5.3, Cochrane Collaboration, Copenhagen, Dinamarca) foi utilizado para gerar o risco de viés com adaptação para as nove perguntas de MAStARI.

### *3.8 Medidas sumárias*

A presença da má oclusão foi considerada o principal desfecho. As más oclusões avaliadas foram: overjet acentuado (> 2mm); mordida aberta anterior ( usente: presença de sobremordida ou de mordida de ponta a ponta anterior ou Presente); Mordida cruzada posterior:(Ausente: relação transversal normal entre os dentes posteriores maxilares e mandibulares ou Presente: um ou mais dentes posteriores superiores anormalmente palatais em relação ao antagonista).

### *3.9 Síntese dos resultados*

Foram definidas variáveis categóricas (overjet acentuado, mordida aberta anterior, mordida cruzada posterior e frequência do hábito) e variáveis contínuas (frequência, intensidade e duração do hábito). Uma meta-análise foi realizada com o MedCalc Statistical Software versão 14.8.1 (MedCalc Software, Ostend, Bélgica) para avaliar a prevalência de má oclusão em crianças que usavam chupetas ortodônticas, convencionais e livres do hábito. Foram utilizados modelos de efeitos fixos e aleatórios. A heterogeneidade estatística foi avaliada pelo Índice de Inconsistência (I<sup>2</sup>) e um valor maior que 50% foi considerado um indicador de heterogeneidade substancial entre os estudos. O nível de significância foi estabelecido em 5%.

### *3.10 Risco de viés entre os estudos*

Foram estudadas a heterogeneidade clínica (diferenças nos participantes, intervenções e resultados) e heterogeneidade metodológica (desenho do estudo, risco de viés).

## 4 ARTIGO

**Artigo a ser submetido à revista:**

*Pediatric Dentistry*

**Title: The malocclusion and use of orthodontic or conventional pacifier: a meta- analysis**

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Raphaela Medeiros: Dr. Medeiros worked on study conceptualization, design, data collection, data analysis, drafted the initial manuscript, and critically reviewed manuscript.

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Ricardo Vieira: Dr. Vieira: revised the manuscript, and approved the final manuscript as submitted.

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All authors have made substantive contribution to this manuscript, and all have reviewed the final paper prior to its submission

## **ABSTRACT**

**Purpose:** To estimate the prevalence of malocclusion in users of orthodontic and conventional pacifier.

**Methods:** Observational studies in children aged 0-60 months who used orthodontic or conventional pacifier.. The search was performed in five databases and grey literature.

**RESULTS:** 3 studies were included in this Review. Users of conventional pacifier presented 57.6 percent (95 percent CI 44.8 to 69.6; total=64) of accentuated overjet, while those who use orthodontic pacifier presented 47.2 percent (95 percent CI 35.3 to 59.3; total=70), and no habit 11.4 percent (95 percent CI 6.7 to 17.9; total=137). Anterior open bite in users of conventional pacifier was 51.6 percent (95 percent CI 15.8 to 86.5; total=102), orthodontic pacifier 40.8 percent (95 percent CI 9.6 to 77.0; total=152) and no habit 3.0 percent (95 percent CI 1.2 to 6.2; total=224). Posterior crossbite was reported in 12.7 percent of users of conventional pacifier (95 percent CI 7.0 to 20.6; total=102), 12.1 percent of orthodontic pacifier users (95 percent CI 7.4 to 18.4; total=152), and 2.7 percent of children without pacifier habit (95 percent CI 1.0 to 5.8; total=226).

**CONCLUSIONS:** There is greater prevalence of accentuated overjet and anterior open bite in children using conventional pacifier compared to orthodontic. There is no difference in posterior crossbite.

There is higher prevalence of malocclusion among users of two types pacifiers than children without sucking habit

**KEYWORDS:** malocclusion; pacifier; systematic review; primary teeth.

## INTRODUCTION

Non-nutritive sucking is a natural reflex for infants, it can be an important first step in the infant's development of self-regulation and ability to control emotion<sup>1</sup>. The use of pacifier is a common habit present in children, and it is supported by American Academy of Pediatrics<sup>2</sup> due to benefic effects in first six months of life<sup>3</sup>. The pacifier has a tranquilize effect, and promotes child safety<sup>4</sup>. However, the excessive use may cause changes in primary dentition occlusion and continuing in permanent dentition if it lasts<sup>5-8</sup>.

Evidence indicates that pacifier may be etiological factor for the development of malocclusion, due to interference of the physiological movements of the perioral muscles<sup>9</sup>. Among pacifiers users, approximately 27 percent of children aged 2-5 years old developed some type of malocclusion<sup>5</sup>. The prevalence of anterior open bite ranges from 17 percent to 96 percent<sup>5,10</sup>, posterior cross bite presents indices from 27 percent to 88 percent<sup>10</sup>, and the presence of accentuated overjet is diagnosed in 52 percent of these individuals<sup>10</sup>.

Researches also demonstrated that malocclusion associated to pacifier use could be influenced by frequency, duration and intensity<sup>10,11</sup>. It was observed that the longer the duration the greater the frequency, and the greater the intensity of the sucking habit, increased the chance of developing malocclusion<sup>11-13</sup>. The use of a pacifier beyond the age of 3 years old influences the development of malocclusion<sup>14</sup>.

There are two different types of pacifiers classified according to the anatomical form (conventional pacifier and orthodontic pacifier). Conventional pacifier (CP) is also known as "cherry" nipple. These nipples have a trunk that become ball shaped. They have no right way up and are not orthodontic. The orthodontic pacifier (OP) are confectioned with flattened nipple with the propose of simulate mothers' nipple anatomy aiming to reduce the risk of malocclusion due to the tongue positioning during the act and acceptable lip seal<sup>10,15-17</sup>.

Although pacifiers are largely used and marketed with a nipple-like design to reduce the risk of malocclusion there is a lack of articles that compare the types of pacifiers. A previous meta-analysis reported that there is no possibility of concluding the existence of differences

regarding the consequences of the use of different shapes of pacifiers to the stomatognathic system<sup>18</sup>. However, this review used different criteria for included studies, such as, for example age, parameters. And among studies with the same sample, the study with the smallest sample was included, which may alter the results found. In addition, with research update done until 2014, and new study were published in literature.

Based on the importance of the subject and the frequent use of pacifier in the daily lives of children, this study aimed to carry out a systematic review with update of literature for answering the following question: In infants and children, is there difference in the prevalence of malocclusion between the type of pacifier used (conventional or orthodontic)?

## **METHODS**

The Preferred Reporting Items for Systematic Reviews and Meta-Analysis<sup>19</sup> (PRISMA) Checklist was followed in this systematic review. In addition, this protocol was completed and registered at the International Prospective Register of Systematic Reviews (PROSPERO CRD42016045826) (ANEXO 1).

### **Eligibility criteria**

To be included, the selected articles had to meet the following criteria: observational studies performed in children aged 0-60 months who used orthodontic or conventional pacifier. All factors associated with pacifier use were accepted: any evaluation of frequency, duration or intensity described in the studies. Articles published and unpublished, in all languages, with no date restriction were included.

### **Exclusion criteria**

The exclusion criteria followed the *PECOS*<sup>20</sup> strategy: (P - participants) 1) studies in which sample includes children with genetic syndromic (e.g., Down syndrome, craniofacial anomalies, neuromuscular disorders, etc.); 2) studies in which sample includes children with presenting malignancies, malnutrition and chronic diseases; 3) children with other non-nutritional sucking habits, or lingual interposition, or enlarged adenoids, or respiratory problems; 4) in children with history of use of orthodontic appliances; 5) conducted in children over 60 months; 6) which the sample included maxillofacial surgery; (E - exposure): 7) studies that did not measure pacifier use

characteristics; 8) in children who used both models of pacifiers simultaneously (orthodontic and conventional) or not differentiate groups by types of pacifiers; (C - comparison) studies: 9) without an active control group (conventional pacifier); and (S - Types of Studies) 10) duplicated references with the same sample; 11) Reviews, letters, personal opinions, case reports, book chapters and conference abstracts; and 12) articles not found.

### **Information sources and search strategies**

An electronic search was conducted on May 5<sup>th</sup> 2016, with update done on Dec 17<sup>th</sup> 2016. Detailed individual search strategies for each of the following electronic databases were performed: Latin American and Caribbean Health Sciences (LILACS), PsycINFO, PubMed (including MedLine), Scopus and Web of Science. A partial grey literature search was taken using Google Scholar and the database System for Information on Grey Literature in Europe (OpenGrey). Dissertations and theses were searched using the ProQuest Dissertations and Theses database. In addition, hand searching of the reference lists of selected studies were performed. The search terms were developed with the aid of an experienced health sciences librarian and were comprehensive to include studies reporting on orthodontic or conventional pacifier use and malocclusion under a range of other synonyms (Appendix 1). References were managed by reference manager software EndNote® Basic (Thomson Reuters, New York, EUA) and duplicate hits were removed.

### **Study selection**

Articles were selected in two phases. Two reviewers (RM and MX) independently examined the titles and abstracts of all references to eliminate obviously irrelevant studies in phase-1. In phase-2, full-texts were independently reviewed by the same reviewers (RM and MX), and screened accordingly. Disagreements were settled by discussion, and a third reviewer (CM) was consulted, if necessary, to make a final decision.

### **Data collection process**

One reviewer (RM) performed data extraction and a second reviewer (MX) crosschecked all the retrieved information, with disagreement resolved by consensus. A third author (CM) was involved, when required, to make a final decision.

### **Data items**

The following data were extracted: study characteristics (author, year, country, design, setting), population characteristics (sample size, age), and outcome characteristics (main results and conclusion).

Unsuccessfully attempts were made to contact the authors to retrieve any pertinent unpublished information in case the required data were not complete.

### **Risk of bias in individual studies**

The Meta-analysis of Statistics Assessment and Review Instrument (MAStARI) from the Joanna Briggs Institute was the risk of bias tool used<sup>21</sup>. Two reviewers (RM and MX) independently categorized methodological quality of the selected studies as high risk of bias when the study reached up to 49 percent score “yes”, moderate 50 percent to 69 percent score “yes”, and low for more than 70 percent score “yes”. Inconsistencies in ratings were resolved by consensus when possible, or a third reviewer (CM) made the final decision. The RevMan Software (Review Manager, version 5.3 software, Cochrane Collaboration, Copenhagen, Denmark) was used to generate the risk of bias summary with adaptation for the nine questions of MAStARI.

### **Summary measures**

Presence of malocclusion was considered the main outcome. The assessed malocclusions were: Accentuated overjet (> 2mm); Anterior openbite (absent: presence of overbite or anterior end-to-end bite or present); posterior crossbite (absent: normal transverse relationship between the maxillary and mandibular posterior teeth or present: one or more maxillary posterior teeth abnormally for palatal relative to the antagonist). Posterior crossbite were assessed unilaterally or bilaterally.

### **Synthesis of results**

Any type of related outcome measurement was computed, categorical variables (accentuated overjet, anterior open bite, posterior crossbite and frequency of the habit) and continuous variables (frequency, intensity and duration of the habit). A meta-analysis was performed using the MedCalc Statistical Software version 14.8.1 (MedCalc Software, Ostend, Belgium) to assess the prevalence of malocclusion in children that used orthodontic and conventional pacifiers. Both fixed and random effects model were employed. Statistical heterogeneity was assessed using the Inconsistency Index ( $I^2$ ), and a value greater than 50% was considered an indicator of substantial heterogeneity between studies. The significance level was set at 5 percent.

### **Risk of bias across studies**

Clinical heterogeneity (differences in participants, interventions and outcomes) and methodological heterogeneity (study design, risk of bias) were explored.

## **RESULTS**

### **Studies selection**

The search found 607 articles across five databases. Duplicates were removed and 444 studies were screened. Furthermore, other studies were identified: Google scholar (17), Opengrey (2), Proquest (1), and reference lists (2). From these, only one study met the inclusion criteria. After titles and abstracts reading, 119 papers were selected to second phase (full-text reading). According to exclusion criteria, 116 studies were excluded and four studies were suitable to answering the review question. However, two studies had the same sample, therefore the study with smaller sample were excluded. Thus, only three studies were included in this systematic review. Figure 1 shows a flowchart describing the process of identification, inclusion, and exclusion of studies and the reasons for exclusion are compiled in a comprehensive list (Appendix 2).

### **Study characteristics**

Among the three studies, two were cross-sectional<sup>15,16</sup> and one cohort<sup>10</sup>. Selected studies were carried out in Brazil (two studies)<sup>10,15</sup> and United States (one study)<sup>16</sup> with papers published between 1995<sup>16</sup> and 2016<sup>10</sup>. The age ranged from 24<sup>10,16</sup> to 60<sup>15</sup> months, and sample size between 61<sup>15</sup> and 218<sup>16</sup> children. Table 1 summarizes the descriptive characteristics of the included studies.

### **Risk of bias within studies**

According to MASTARI, one study presented low<sup>10</sup> and two moderate risk of bias<sup>15,16</sup>. From studies included in this review, two had a moderate risk of bias<sup>15,16</sup> and 1 had low risk<sup>10</sup>. The moderate risk was associated to the uncertainty of sample randomization; this may be because the most commonly found sample was by convenience. In relation to confounding factors, the authors excluded: children with other non-nutritive sucking habits; mouth breathers; children with lingual interposition. Although questionnaires were applied regarding the frequency and duration of the habit, there may have been a reporting memory error by the parents/guardians.

Summarized assessment considering risk of bias can be found in Figure 2. Detailed results on the use of MASTARI tool in selected studies can be found in Appendix 3.

### **Results of individual studies**

All selected studies analyzed anterior open bite, accentuated overjet, and posterior crossbite<sup>10,15,16</sup>

Adair et al<sup>16</sup> examined children with mean age of 43.9 months, Zardeto et al<sup>15</sup> 46 months and Lima et al<sup>10</sup> 29 months.

The occurrence of anterior open bite varied among users of CP in studies of Adair et al<sup>16</sup> (23.7 percent) and Lima et al<sup>10</sup> (80.0 percent) compared to OP 13.4 percent and 63.6 percent respectively. This is difference may be due to sample size and age group. However, Adair et al<sup>16</sup> did not find statistically significant difference between groups. Nevertheless, Zardeto et al<sup>15</sup> identified that both groups had a 50 percent prevalence and no difference in means to degree in millimeters.

Lima et al<sup>10</sup> and Zardeto et al<sup>15</sup> used the same selection criteria to determine accentuated overjet ( $> 2\text{mm}$ ), while Adair et al<sup>16</sup> used  $\geq 4\text{ mm}$ . Zardeto et al<sup>15</sup> showed statistically significant difference between groups, 58 percent in OP and 64 percent in CP, however there was no difference in mean overjet (mm) among the groups. Lima et al<sup>10</sup> measured overjet in mm and it were higher in CP (3.38mm) compared to OP (2.54mm) and estimated the prevalence in 41,8 percent in OP and 56,3 percent in CP.

Regarding posterior crossbite, Adair et al<sup>16</sup> showed that occurrence of posterior crossbites did not differ between the two groups of pacifiers. Zardeto et al<sup>15</sup> and Lima et al<sup>10</sup> observed that prevalence was more predominant among those in the CP group (14 and 9 percent), as compared the OP group (10 and 5.4 percent), although Zardetto et al<sup>15</sup> did not find significant difference. This can be explained because the posterior crossbite is easier to diagnose, moreover, depending on the age group, the bite not still crossed.

Regarding frequency, Lima et al<sup>10</sup> observed that approximately 78.2 percent of the children in CP and 67.3 percent of the children in OP sucked day and night, this difference was not statistically significant. Similarly, Zardetto et al<sup>15</sup> found that 71 percent users of CP and 68 percent users of orthodontic pacifier had the habit while sleeping. Adair et al<sup>16</sup> showed differences in reported hours of use per day, CP pacifier was used 6,5 hours/day and OP 6,7 hours/day.

Regarding duration, Lima et al<sup>10</sup> showed difference statistically significant among groups, CP 27 months and OP 25 months. Adair et al<sup>16</sup> and Zardeto et al<sup>15</sup> found no statistically difference. The mean time of use (months) ranged from 19,8 to 45 in CP and from 15,4 to 43 in OP. There was a significantly higher percentage of posterior crossbites (21.1 percent) among those who had used pacifiers for more than 15.5 months compared with those who had the habit for less than 15.5 months (6.1 percent)<sup>16</sup>. Mean openbite was greater in current pacifier users (3.6 mm) than recent (2.0 mm) or early (2.2 mm) discontinuers of pacifier use, though these differences were not statistically significant. Current users constituted 50 percent of all crossbite cases, while recent and early discontinuers made up 27.7 percent and 22.2 percent of crossbite cases, respectively<sup>16</sup>.

### **Synthesis of results**

The meta-analysis comprised the three malocclusions most associated with the use of pacifiers: anterior open bite, accentuated overjet and posterior crossbite. The three studies were part of the meta-analysis, however only two studies<sup>10,15</sup> participated in the accentuated overjet analysis due to different measurement parameters.

The results from these meta-analysis revealed that the children users of conventional pacifier had 10 percent more prevalence of accentuated overjet (>2mm) when compared with children users of orthodontic pacifier, 9 percent more of anterior open bite and the same prevalence of posterior crossbite (Figure 3).

Prevalence of accentuated overjet (>2mm) in children that used CP was 57,6 percent (95 percent CI 44.8 to 69.6; fixed effects; total sample=64), OP 47.2 percent (95 percent CI 35.3 to 59.3; fixed effects; total sample=70) and children with no habit 11,4 percent (95 percent CI 6.7 to 17.9; fixed effects; total sample=137) (Appendix 4). Prevalence of anterior open bite in children that used CP was 51.6 percent (95 percent CI 15.8 to 86.5; random effects; total sample=102), OP 40.8 percent (95 percent CI 9.6 to 77.0; random effects; total sample=152) and children with no habit 3.0 percent (95 percent CI 1.2 to 6.2; fixed effects; total sample=224) (Appendix 5). Prevalence of posterior crossbite in children that used CP was 12.7 percent (95 percent CI 7.0 to 20.6; fixed effects; total sample=102), OP 12.1 percent (95 percent CI 7.4 to 18.4; fixed effects; total sample=152) and children with no habit 2.7 percent (95 percent CI 1.0 to 5.8; fixed effects; total sample=226) (Appendix 6).



## DISCUSSION

This systematic review evaluated the evidence on the performance of the orthodontic and conventional pacifier in the development of malocclusions. Although the meta-analysis identified that those children users of conventional pacifiers had more prevalence of malocclusion in comparison to orthodontic pacifier users; it is not possible to affirm that there are advantages in the orthodontic pacifier, due to the small and dubious sample selection.

Studies involving pacifiers sucking habit had shown that the main malocclusions associated with its use were usually limited to changes in the position of the incisors<sup>22</sup> like an anterior open bite, overjet and posterior crossbite<sup>10,22-24</sup>.

All studies in this review showed no significant differences between types of the pacifier. Only one study<sup>10</sup>, with low risk of bias, indicated that open bite was more present in children who used conventional pacifiers when compared to children that used orthodontic pacifiers. Beyond the percentages of the open bite, the studies also investigated the amount of openbite in millimeters, equally without difference among groups. Thus, the literature did not show advantages on the use of orthodontic pacifier over conventional in regarding to malocclusion.

This review demonstrated that prolonged pacifier use influences the development of occlusion. It had indicated that the prevalence of accentuated overjet and anterior open bite in children who used the orthodontic pacifier was 10 percent lower compared to conventional pacifiers considering a duration of use of up to 45 months and a high frequency of use during sleeping time. However, with regard to posterior crossbite, there is no difference between types of pacifiers. It would be more appropriate to use pacifiers for shorter time duration.

The studies showed that occlusal changes deformities associated with oral habits depend on the intensity, duration and frequency of the habit<sup>25</sup>. The studies presented different forms to measure these parameters. In one study, the authors measured frequency in hours per day of use<sup>16</sup>, whereas other two articles evaluated in daytime and/or nighttime<sup>10,15</sup>. Nevertheless, the frequency was similar between groups, conventional and orthodontic pacifier. The average hours of use per day shown in the studies was the quantity considered by the literature as a factor of alteration in the dental arch. The number of hours of use is an

important variable for the installation of the malocclusion, 4 to 6 hours of use per day is considered an indication for malocclusion<sup>4,8,13</sup>. The literature investigated showed that majority of the children used pacifier during sleeping time. The recommendations of pacifier use report that it should be used when the infant is sleeping and not reinserted if the child left it drop during sleep<sup>26</sup>.

Concerning duration, there was a relationship with malocclusion, especially in anterior open bite and posterior cross bite according to a cross-sectional study<sup>16</sup>. In general, the duration was greater in users CP, however there was no difference in number of months of pacifier use among the two types of pacifier. The studies suggested that the use of more than 36 months interferes in occlusion and the longer the duration in months, the greater the chance of this interference<sup>9,12</sup>. This shows that malocclusion may be more related to the time of use than the design of the pacifier. A study related that transverse occlusal relationship should be evaluated between 2 and 3 years of age mainly in children pacifiers users<sup>13</sup>.

Although the literature is clearly and strongly supported that the pacifier interferes in the occlusion of the children users<sup>24,27-31</sup>, there is no indication of prohibiting the pacifier<sup>3</sup>. Besides being of great value to cherish the infant and be an ally to the parents to calm the crying, it has beneficial effects to the child's health, such as reducing the risk of sudden death syndrome<sup>32</sup> and minimizing and controlling possible routine pains<sup>4</sup>.

The American Academy of Pediatrics and the American Academy of Family Physicians<sup>3</sup> recommend the use of pacifier in first month and limits the use in second six months of life to reduce the risk of otitis media<sup>33</sup>. The Canadian Paediatric society<sup>34</sup> recommends that until further research leads to more conclusive evidence on adverse outcomes, health care professionals should recognize pacifier use as a parental choice determined by the needs of their newborn, infant or child.

Although there are also harmful effects of the use of pacifiers, especially malocclusion, there are increasing indications that the adverse effects are related to the non-rational use, i.e. the indiscriminate use without proper guidance of the pacifier indication by a health care professional. The use rational consist in use for sleeping and for less than 4 to 6 hours per day

The limitations of these studies are due to non-standardization of ages and different parameters to measure intensity, duration and

frequency. In addition, some studies did not use the same measures to define malocclusion.

May have occurred in the memory of parents to identify the type of pacifier, as well as, there was no control of the genetic factors and of the facial growth pattern of the children examined. More studies should be carried out on this topic for more faithful conclusions

This is meta-analysis also compared users of pacifiers to non-users. It was observed that the prevalence of malocclusion in non-users was smaller than in other groups, reaching up to less than 3 percent in the case of posterior crossbite.

### CONCLUSIONS

- Based on limited evidence, there appears to be a greater prevalence of accentuated overjet and anterior open bite in children using conventional pacifier compared to orthodontic pacifiers. However, there is no difference in posterior crossbite.
- There is a higher prevalence of malocclusion among users of orthodontic and conventional pacifiers than children without the habit.

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## Appendix 1 - Search Strategy (December 17<sup>th</sup>, 2016).

| Database        | Search  |
|-----------------|---|
| <b>LILACS</b>   | (tw:(pacifier* OR pacificer* OR sucking OR dummy OR consoler* OR sucker* OR chupet* OR succion* OR sucção )) AND (tw:(child* OR infant* OR preschool* OR pediatric* OR paediatric* OR minor* OR newborn* OR baby OR babies OR niño* OR "recién nacidos" OR "recién nacido" OR criança* OR "recém-nascidos" OR bebê* OR infanti* OR "pré escolar" OR "pre escolares" OR pré-escolar* )) AND (tw:( "open bite" OR "open bites" OR openbite* OR malocclusion* OR "arch relationship" OR "arch relationships" OR "cross bite" OR "cross bites" OR crossbite* OR overbite* OR "over bite" OR "over bites" OR overjet* OR "dental occlusion" OR "dental occlusion" OR misalignment* OR "dental arch" OR "dental arches" OR "mordida aberta" OR "mordidas abertas" OR "má oclusão" OR maloclusão OR "má oclusões" OR "maloclusões" OR sobremordida* OR "oclusão dentária" OR "oclusões dentárias" OR desalinhamento OR "mordida aberta" OR "relacao entre arcos" OR "relacoes entre arcos" OR "arco dental" OR "arcos dentais" OR "arcos dentarios" OR "arcos dentales")) AND (instance:"regional") AND ( db:("LILACS")) |
| <b>PsycINFO</b> | "open bite" OR "open bites" OR openbite* OR malocclusion* OR "arch relationship" OR "arch relationships" OR "cross bite" OR "cross bites" OR crossbite* OR overbite* OR "over bite" OR "over bites" OR overjet* OR "dental occlusion" OR "dental occlusion" OR misalignment* OR "dental arch" OR "dental arches"  |

|               |  |
|---------------|--|
| <b>PubMed</b> | (("pacifiers"[MeSH Terms] OR "pacifier"[All Fields] OR "pacifiers"[All Fields] OR "pacifiers"[All Fields] OR dummy[All Fields] OR consoler[All Fields] OR consolers[All Fields]) AND ("open bite"[MeSH Terms] OR "open bite"[All Fields] OR ("open bite"[MeSH Terms] OR ("open"[All Fields] AND "bite"[All Fields]) OR "open bite"[All Fields] OR "openbite"[All Fields]) OR openbites[All Fields] OR "open bites"[All Fields] OR "malocclusion"[MeSH Terms] OR "malocclusion"[All Fields] OR "malocclusions"[All Fields] OR "arch relationship"[All Fields] OR "arch relationships"[All Fields] OR "cross bite"[All Fields] OR "cross bites"[All Fields] OR "crossbite"[All Fields] OR "crossbites"[All Fields] OR "overbite"[MeSH Terms] OR "over bite"[All Fields] OR "over bites"[All Fields] OR "overbite"[All Fields] OR "overbites"[All Fields] OR "overjet"[All Fields] OR "dental occlusion"[All Fields] OR misalignment[All Fields] OR misalignments[All Fields] OR "dental arch"[MeSH Terms] OR "dental arch"[All Fields] OR "dental arches"[All])) AND ("child"[MeSH Terms] OR "child"[All Fields] OR "children"[All Fields] OR "childhood"[All Fields] OR "infant"[MeSH Terms] OR "infant"[All Fields] OR "infants"[All Fields] OR "child, preschool"[MeSH Terms] OR preschool[All Fields] OR preschools[All Fields] OR "pediatrics"[MeSH Terms] OR "pediatrics"[Title/Abstract] OR "pediatric"[Title/Abstract] OR "paediatrics"[Title/Abstract] OR "paediatric"[Title/Abstract] OR "minors"[MeSH Terms] OR "minors"[All Fields] OR "infant, newborn"[MeSH Terms] OR "newborn"[All Fields] OR "newborns"[All Fields] OR "baby"[All Fields] OR "babies"[All Fields]) |
| <b>Scopus</b> | (TITLE-ABS-KEY(pacifier* OR pacificer* OR dummy OR consoler* ) AND TITLE-ABS-KEY(Child* OR infant* OR preschool* OR pediatric* OR paediatric* OR minor* OR newborn* OR baby OR babies)AND TITLE-ABS-KEY("open bite" OR "open   |

|                       |  |
|-----------------------|--|
|                       | bites" OR openbite* OR malocclusion* OR "arch relationship" OR "arch relationships" OR "cross bite" OR "cross bites" OR crossbite* OR overbite* OR "over bite" OR "over bites" OR overjet* OR "dental occlusion" OR "dental occlusion" OR misalignment* OR "dental arch" OR "dental arches")) AND ( LIMIT-TO(DOCTYPE,"ar" ) OR LIMIT-TO(DOCTYPE,"ip")) AND (LIMIT-TO(SUBJAREA,"MEDI") OR LIMIT-TO(SUBJAREA,"DENT") OR LIMIT-TO(SUBJAREA,"PSYC") OR LIMIT-TO(SUBJAREA,"NURS" ) OR LIMIT-TO(SUBJAREA,"HEAL") OR LIMIT-TO(SUBJAREA,"NEUR")) |
| <b>Web of Science</b> | (pacifier* OR pacifier* OR dummy OR consoler*) AND (Child* OR infant* OR preschool* OR pediatric* OR paediatric* OR minor* OR newborn* OR baby OR babies) AND ("open bite" OR "open bites" OR openbite* OR malocclusion* OR "arch relationship" OR "arch relationships" OR "cross bite" OR "cross bites" OR crossbite* OR overbite* OR "over bite" OR "over bites" OR overjet* OR "dental occlusion" OR "dental occlusion" OR misalignment* OR "dental arch" OR "dental arches")   |
| <b>Google Scholar</b> | "pacifier OR orthodontic pacifier" AND ~child AND malocclusion   |
| <b>OpenGrey</b>       | (pacifier* OR pacifier* OR dummy OR consoler*) AND (Child* OR infant* OR preschool* OR pediatric* OR paediatric* OR minor* OR newborn* OR baby OR babies) AND ("open bite" OR "open bites" OR openbite* OR malocclusion* OR "arch relationship" OR "arch relationships" OR "cross bite" OR "cross bites" OR crossbite* OR overbite* OR "over bite" OR "over bites" OR overjet* OR "dental occlusion" OR "dental occlusion" OR misalignment* OR "dental arch" OR "dental arches")   |
| <b>ProQuest</b>       | (pacifier* OR pacifier* OR dummy OR consoler*) AND (Child* OR infant* OR preschool* OR pediatric* OR paediatric* OR minor* OR newborn* OR baby OR babies) AND ("open bite" OR "open bites" OR openbite* OR malocclusion* OR "arch relationship" OR   |

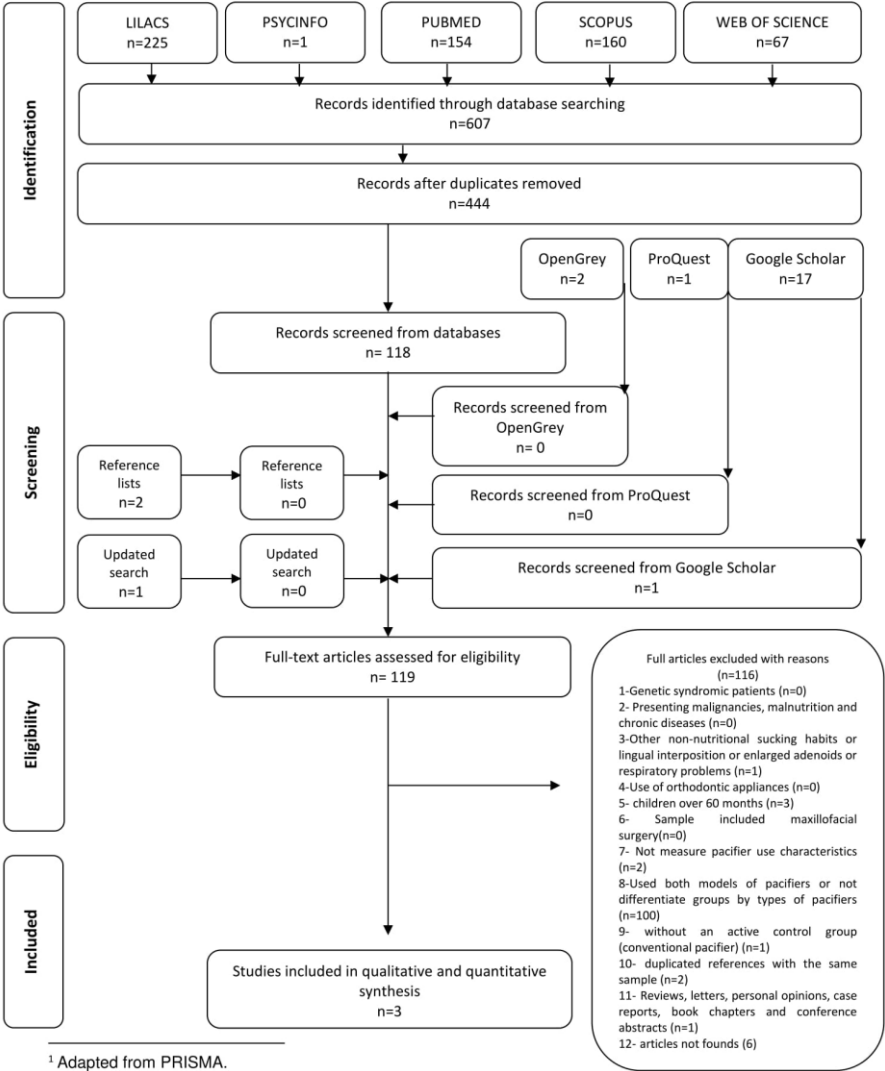


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"arch relationships" OR "cross bite" OR "cross bites"  
OR crossbite\* OR overbite\* OR **"over bite"** OR **"over  
bites"** OR overjet\* OR "dental occlusion" OR "dental  
occlusion" OR misalignment\* OR "dental arch" OR  
"dental arches")

---

Figure 1 - Flow diagram of literature search and selection criteria.<sup>1</sup>



<sup>1</sup> Adapted from PRISMA.

**Appendix 2 - Excluded articles with reasons for exclusion (n=116).**

| <b>Author, Year</b>                          | <b>Reason for Exclusion*</b> |
|--|------------------------------|
| Abrahao et al, 2009 <sup>1</sup>             | 8                            |
| Adair et al, 1992 <sup>2</sup>               | 10                           |
| Agurto V et al 1999 <sup>3</sup>             | 8                            |
| Alcaraz Castillo et al 2012 <sup>4</sup>     | 8                            |
| Almeida et al 2012 <sup>5</sup>              | 8                            |
| Antunes et al 2015 <sup>6</sup>              | 8                            |
| Aznar et al 2006 <sup>7</sup>                | 5                            |
| Barbosa et al 2009 <sup>8</sup>              | 8                            |
| Bezerra et al 2006 <sup>9</sup>              | 8                            |
| Bishara et al, 2006 <sup>10</sup>            | 8                            |
| Boeck et al 2013 <sup>11</sup>               | 8                            |
| Bowden et al, 1966 <sup>12</sup>             | 8                            |
| Bowden et al, 1966 <sup>13</sup>             | 10                           |
| Bueno et al, 2013 <sup>14</sup>              | 8                            |
| Cardoso et al 2014 <sup>15</sup>             | 8                            |
| Carvalho et al 2009 <sup>16</sup>            | 8                            |
| Cavalcanti et al 2006 <sup>17</sup>          | 8                            |
| Castañode Casaretto et al 1996 <sup>18</sup> | 12                           |
| Chevitarese et al, 2002 <sup>19</sup>        | 8                            |
| Coser et al 2004 <sup>20</sup>               | 5                            |
| Cozza et al, 2007 <sup>21</sup>              | 12                           |
| De Barros Miotto 2015 <sup>22</sup>          | 8                            |
| de Sousa et al, 2014 <sup>23</sup>           | 8                            |
| Dimberg et al, 2010 <sup>24</sup>            | 8                            |
| Dimberg et al 2013 <sup>25</sup>             | 8                            |
| Diouf et al, 2010 <sup>26</sup>              | 8                            |
| Dolci et al 2001 <sup>27</sup>               | 12                           |
| dos Santos et al 2012 <sup>28</sup>          | 8                            |
| Duncan et al 2008 <sup>29</sup>              | 8                            |
| Eismann et al 1992 <sup>30</sup>             | 7                            |
| Emmerich et al 2004 <sup>31</sup>            | 8                            |
| Esperança et al 2005 <sup>32</sup>           | 8                            |
| Farsi et al 1997 <sup>33</sup>               | 8                            |
| Feldens et al 2016 <sup>34</sup>             | 8                            |
| Fialho et al 2014 <sup>35</sup>              | 8                            |
| Franco Varas et al 2012 <sup>36</sup>        | 8                            |

|   |    |
|---|----|
| Franco Varas et al 2012 <sup>37</sup>     | 8  |
| Furtado et al 2007 <sup>38</sup>          | 8  |
| Germa et al 2016 <sup>39</sup>            | 8  |
| Gimenez et al 2008 <sup>40</sup>          | 8  |
| Gonçalves et al 2010 <sup>41</sup>        | 8  |
| Gondim et al 2010 <sup>42</sup>           | 8  |
| Gois et al 2008 <sup>43</sup>             | 8  |
| Holm et al 1974 <sup>44</sup>             | 8  |
| Ito et al 2010 <sup>45</sup>              | 8  |
| Ize-Iyamu et al 2012 <sup>46</sup>        | 8  |
| Jabbar et al 2011 <sup>47</sup>           | 8  |
| Karjalainen et al 1999 <sup>48</sup>      | 8  |
| Katz et al 2005 <sup>49</sup>             | 12 |
| Kobayashi et al 2008 <sup>50</sup>        | 12 |
| Larsson et al 1982 <sup>51</sup>          | 11 |
| Larsson et al 1986 <sup>52</sup>          | 8  |
| Leite-Cavalcanti et al 2007 <sup>53</sup> | 8  |
| Lima et al 2010 <sup>54</sup>             | 8  |
| Lindner et al, 1989 <sup>55</sup>         | 8  |
| Lopez Del Valle et al 2006 <sup>56</sup>  | 8  |
| Luzzi et al, 2011 <sup>57</sup>           | 8  |
| Macena et al 2009 <sup>58</sup>           | 8  |
| Macho et al 2012 <sup>59</sup>            | 8  |
| Maciel et al 2005 <sup>60</sup>           | 8  |
| Magalhães et al 2012 <sup>61</sup>        | 8  |
| Massuia et al 2011 <sup>62</sup>          | 8  |
| Melink et al 2010 <sup>63</sup>           | 8  |
| Mendes et al 2008 <sup>64</sup>           | 8  |
| Mesomo et al 2004 <sup>65</sup>           | 7  |
| Meyers et al 1988 <sup>66</sup>           | 5  |
| Miotto et al 2014 <sup>67</sup>           | 8  |
| Modeer et al 1982 <sup>68</sup>           | 8  |
| Moimaz et al 2014 <sup>69</sup>           | 8  |
| Moimaz et al 2013 <sup>70</sup>           | 8  |
| Morais et al 2014 <sup>71</sup>           | 8  |
| Neto et al 2012 <sup>72</sup>             | 8  |
| Nihi et al 2015 <sup>73</sup>             | 8  |
| Ogaard et al 1989 <sup>74</sup>           | 12 |
| Ogaard et al 1994 <sup>75</sup>           | 8  |
| Oliveira et al 2006 <sup>76</sup>         | 8  |
| Oliveira et al 2010 <sup>77</sup>         | 8  |

|  |   |
|--|---|
| Ovsenik et al 2007 <sup>78</sup>             | 8 |
| Paunio et al 1993 <sup>79</sup>              | 8 |
| Pereira et al 2003 <sup>80</sup>             | 8 |
| Peres et al 2007 <sup>81</sup>               | 8 |
| Peters et al 1986 <sup>82</sup>              | 8 |
| Pipa Vallejo et al 2011 <sup>83</sup>        | 8 |
| Primožic et al 2013 <sup>84</sup>            | 8 |
| Rochelle et al 2010 <sup>85</sup>            | 8 |
| Romero et al 2011 <sup>86</sup>              | 8 |
| Rossi et al 2009 <sup>87</sup>               | 8 |
| Santos et al 2007 <sup>88</sup>              | 8 |
| Santos et al 2012 <sup>89</sup>              | 8 |
| Sato et al 2012 <sup>90</sup>                | 8 |
| Scavone-Junior et al 2005 <sup>91</sup>      | 8 |
| Scavone-Junior et al 2007 <sup>92</sup>      | 8 |
| Schlömer et al 1984 <sup>93</sup>            | 8 |
| Silva et al 2005 <sup>94</sup>               | 8 |
| Silvestrini-Biavati et al 2016 <sup>95</sup> | 8 |
| Siqueira et al 2002 <sup>96</sup>            | 8 |
| sMartins et al 2003 <sup>97</sup>            | 3 |
| Soligo et al 1999 <sup>98</sup>              | 8 |
| Sousa et al 2004 <sup>99</sup>               | 8 |
| Souza et al 2006 <sup>100</sup>              | 8 |
| Stecksen-Blicks et al 1995 <sup>101</sup>    | 8 |
| Tibolla et al 2012 <sup>102</sup>            | 8 |
| Tomita et al 2004 <sup>103</sup>             | 8 |
| Tomita et al 2000 <sup>104</sup>             | 8 |
| Tomita et al 2000 <sup>105</sup>             | 8 |
| Urzal et al 2014 <sup>106</sup>              | 8 |
| Urzal et al 2013 <sup>107</sup>              | 8 |
| Vasconcelos et al 2011 <sup>108</sup>        | 8 |
| Verrastro et al 2008 <sup>109</sup>          | 8 |
| Viggiano et al 2004 <sup>110</sup>           | 8 |
| Zapata et al 2010 <sup>111</sup>             | 8 |
| Zimmer et al 2011 <sup>112</sup>             | 9 |
| Wagner et al 2015 <sup>113</sup>             | 8 |
| Warren et al 2000 <sup>114</sup>             | 8 |
| Warren et al 2002 <sup>115</sup>             | 8 |

Warren et al 2005<sup>116</sup>

8

Legend: 1= sample including genetic syndromic patients, 2= children presenting malignancies, malnutrition and chronic diseases, 3= children with other non-nutritional sucking habits or lingual interposition or enlarged adenoids or respiratory problems, 4= children with history of use of orthodontic appliances, 5= conducted in children over 60 months, 6= which the sample included maxillofacial surgery; 7= that did not measure pacifier use characteristics, 8= children who used both models of pacifiers simultaneously (orthodontic and conventional) or not differentiate groups by types of pacifiers; 9 = without an active control group (conventional pacifier); 10 = duplicated references with the same sample, 11= Reviews, letters, personal opinions, case reports, book chapters and conference abstracts, 12= articles not founds.

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**Table 1 - Summary of Descriptive Characteristics of Included Articles (n=3)**

| Study                                      |                 | Population                         |              |            |            | Outcomes          |                   |                 |                        |  |
|--|-----------------|------------------------------------|--------------|------------|------------|-------------------|-------------------|-----------------|------------------------|--|
| Author, Year, Country                      | Study Design    | Setting                            | Age (months) | Total n OP | Total n CP | Prevalence (%) OP | Prevalence (%) CP | Frequency       | Duration (mean months) | Main Conclusion  |
| Adair et al, 1995 <sup>18</sup> , USA      | Cross-sectional | Daycare centers and dental clinics | 24-59 m      | 82         | 38         | AOB =13,4%        | AOB               | OP=6,7h/d       | OP=15,4m               | There appeared to be no advantage to OP over CP  |
|  |                 |                                    |              |            |            | PCB =15,9%        | =23,7%            | CP=6,5 h/d      | CP=19,8m               |  |
|  |                 |                                    |              |            |            | PCB =13,2%        |                   |                 |                        |  |
| Lima et al, 2016 <sup>12</sup> , Brazil    | Cohort          | Private maternity hospitals        | 24-36 m      | 50         | 50         | AO =41,8%         | AO =56,3%         | OP=67,3%        | OP=25m                 | The use of CP was associated to severe anterior open bite and overjet compared to use of OP. |
|  |                 |                                    |              |            |            | AOB =63,6%        | AOB =80%          | (day/nighttime) | CP=27m                 |  |
|  |                 |                                    |              |            |            | PCB =5,4%         | PCB =9%           | CP=78,2%        |                        |  |
| Zardelo et al, 2002 <sup>17</sup> , Brazil | Cross-sectional | Schools                            | 36-60 m      | 20         | 14         | AO =58%           | AO =64%           | OP=68%          | OP=43m                 | The prevalence and degree of some alterations were lower in the OP group than in the CP.     |
|  |                 |                                    |              |            |            | AOB =50%          | AOB =50%          | (sleeping)      | CP=45m                 |  |
|  |                 |                                    |              |            |            | PCB =10%          | PCB =14%          | CP=71%          | (sleeping)             |  |

Legend: CP = conventional pacifier, OP = orthodontic pacifier, h/d=hours per day,AO= accentuated overjet, AOB = anterior open bite, PCB=posterior crossbite.

**Figure 2** - Summary of the risk of bias assessment according to the Meta-Analysis of Statistics Assessment and Review Instrument (MAStARI) – Figure performed with the aid of RevMan (Review Manager, version 5.3 software, Cochrane Collaboration, Copenhagen, Denmark).

A- Cohort Study.

|                 |  |   |  |   |   |   |   |  |   |
|-----------------|--|---|--|---|---|---|---|--|---|
| Lima et al 2016 | +  | +   | +  | ?   | +   | +   | ?   | +  | +   |
|                 | Is sample representative of patients in the population as a whole? | Are the patients at a similar point in the course of their condition/illness? | Has bias been minimized in relation to selection of cases and of controls? | Are confounding factors identified and strategies to deal with them stated? | Are outcomes assessed using objective criteria? | Is follow-up carried out over a sufficient time period? | Are the outcomes of people who withdrew described and included in the analysis? | Are outcomes measured in a reliable way? | Is appropriate statistical analysis used? |

## B- Cross-sectional Studies.

|                    | Is the study based on a random or pseudorandom sample? | Are the criteria for inclusion in the sample clearly defined? | Are confounding factors identified and strategies to deal with them stated? | Are outcomes assessed using objective criteria? | If comparisons are being made, is there sufficient description of the groups? | Is follow-up carried out over a sufficient time period? | Are the outcomes of people who withdrew described and included in the analysis? | Are outcomes measured in a reliable way? | Is appropriate statistical analysis used? |
|--------------------|--|---|---|---|---|---|---|--|---|
| Adair et al 1995   | ?  | +   | +   | +   | +   | ?   | ?   | +  | +   |
| Zardeto et al 2002 | ?  | +   | +   | +   | +   | ?   | ?   | +  | +   |

**Appendix 3** - Risk of bias assessed by Meta-Analysis of Statistics Assessment and Review Instrument (MASARI) critical appraisal tools. Risk of bias was categorized as high when the study reaches up to 49% score "yes", moderate when the study reached 50% to 69% score "yes", and low when the study reached more than 70% score "yes".

A- Cohort Study

| Question   |  | Lima et al 2016 <sup>12</sup> |
|--|--|-------------------------------|
| 1. Is sample representative of patients in the population as a whole?              |  | Y                             |
| 2. Are the patients at a similar point in the course of their condition/illness?   |  | Y                             |
| 3. Has bias been minimized in relation to selection of cases and of controls?      |  | Y                             |
| 4. Are confounding factors identified and strategies to deal with them stated?     |  | U                             |
| 5. Are outcomes assessed using objective criteria?                                 |  | Y                             |
| 6. Is follow-up carried out over a sufficient time period?                         |  | Y                             |
| 7. Are the outcomes of people who withdrew described and included in the analysis? |  | U                             |
| 8. Are outcomes measured in a reliable way?  |  | Y                             |
| 9. Is appropriate statistical analysis used?                                       |  | Y                             |
| % yes/risk   |  | 77%                           |
| Overall  |  | Low                           |

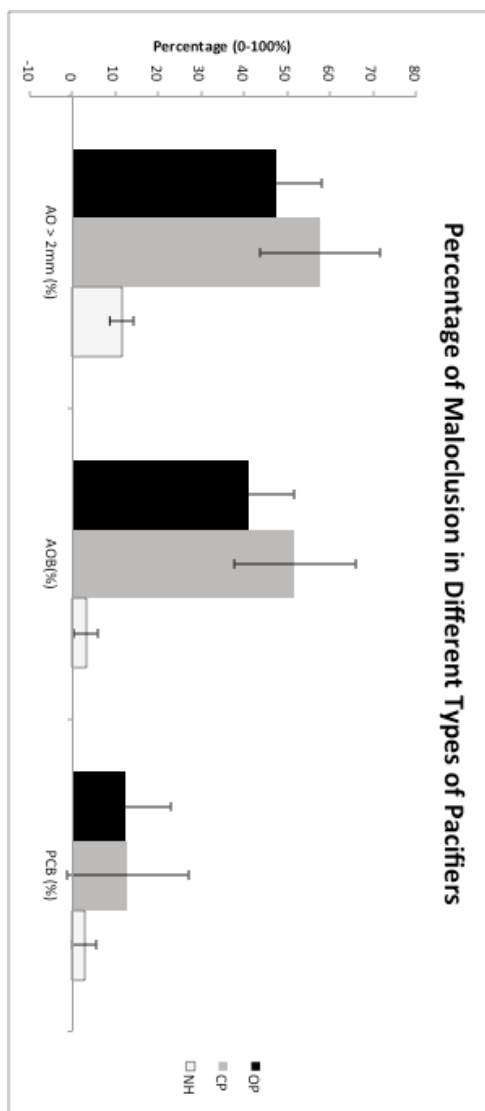
\*Y=Yes, N=No, U=Unclear, NA=Not applicable

## B- Cross-sectional Studies.

| Questions  |  | Adair et al<br>1995 <sup>1</sup> | Zardeto et al<br>2002 <sup>17</sup> |
|--|--|----------------------------------|-------------------------------------|
| 1. Is the study based on a random or pseudorandom sample?                          |  | U                                | U                                   |
| 2. Are the criteria for inclusion in the sample clearly defined?                   |  | Y                                | Y                                   |
| 3. Are confounding factors identified and strategies to deal with them stated?     |  | Y                                | Y                                   |
| 4. Are outcomes assessed using objective criteria?                                 |  | Y                                | Y                                   |
| 5. If comparisons are being made, is there sufficient description of the groups?   |  | Y                                | Y                                   |
| 6. Is follow-up carried out over a sufficient time period?                         |  | NA                               | NA                                  |
| 7. Are the outcomes of people who withdrew described and included in the analysis? |  | U                                | U                                   |
| 8. Are outcomes measured in a reliable way?  |  | Y                                | Y                                   |
| 9. Is appropriate statistical analysis used?                                       |  | Y                                | Y                                   |
| % yes/risk   |  | 66%                              | 66%                                 |
| Overall  |  | Mod                              | Mod                                 |

\*Y=Yes, N=No, U=Unclear, NA=Not applicable

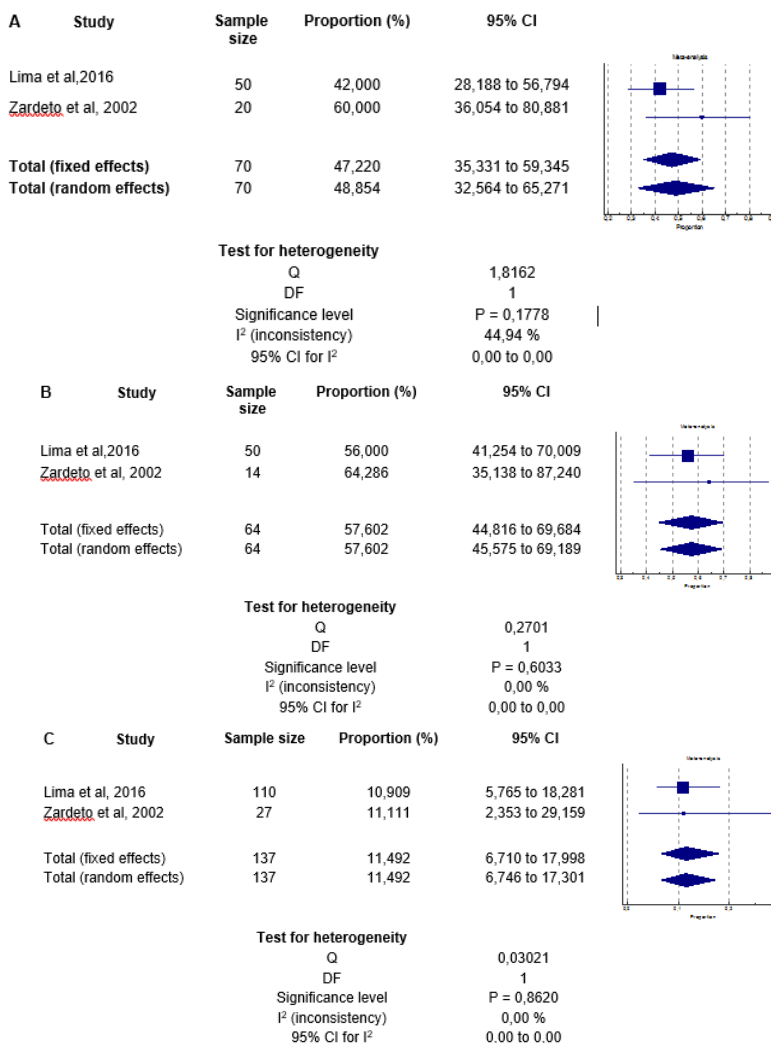
**Figure 3** - Pooled prevalence for each malocclusion that occurred in each type of pacifier. Results from a proportion meta-analysis.



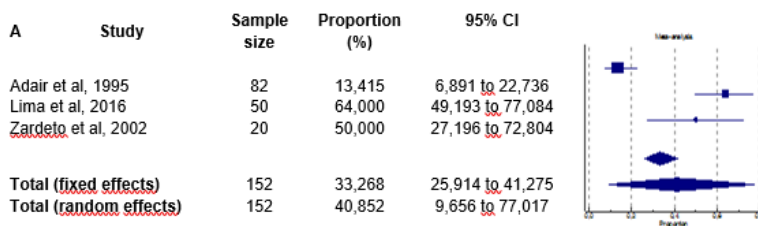




**Appendix 4** - Forest plot for the prevalence of accentuated overjet (>2mm) in children that used (A) orthodontic pacifier – fixed effects; (B) conventional pacifier – fixed effects; and (C) had no habit – fixed effects.

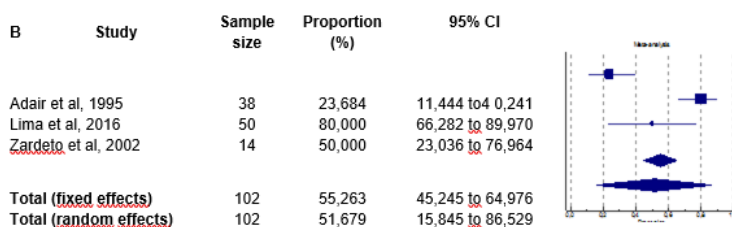


**Appendix 5** - Forest plot for the prevalence of anterior openbite in children that used (A) orthodontic pacifier – random effects; (B) conventional pacifier – random effects; and (C) had no habit – fixed effects.



#### Test for heterogeneity

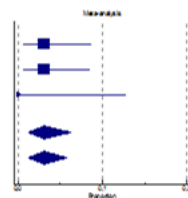
|                                |                |
|--------------------------------|----------------|
| Q                              | 40,1039        |
| DF                             | 2              |
| Significance level             | P < 0, 0001    |
| I <sup>2</sup> (inconsistency) | 95,01%         |
| 95% CI for I <sup>2</sup>      | 88.75 to 97,79 |



#### Test for heterogeneity

|                                |                |
|--------------------------------|----------------|
| Q                              | 30,3348        |
| DF                             | 2              |
| Significance level             | P < 0, 0001    |
| I <sup>2</sup> (inconsistency) | 93,41%         |
| 95% CI for I <sup>2</sup>      | 84,11 to 97,27 |

| C | Study                  | Sample size | Proportion (%) | 95% CI          |
|---|------------------------|-------------|----------------|-----------------|
|   | Adair et al, 1995      | 98          | 3,061          | 0,636 to 8,686  |
|   | Lima et al, 2016       | 99          | 3,030          | 0,629 to 8,601  |
|   | Zardeto et al, 2002    | 27          | 0,000          | 0,000 to 12,770 |
|   | Total (fixed effects)  | 224         | 3,090          | 1,253 to 6,259  |
|   | Total (random effects) | 224         | 3,090          | 1,242 to 5,732  |

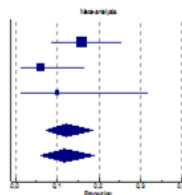


#### Test for heterogeneity

|                                |               |
|--------------------------------|---------------|
| Q                              | 0,8518        |
| DF                             | 2             |
| Significance level             | P = 0,6532    |
| I <sup>2</sup> (inconsistency) | 0,00%         |
| 95% CI for I <sup>2</sup>      | 0,00 to 92,12 |

**Appendix 6** - Forest plot for the prevalence of posterior crossbite in children that used (A) orthodontic pacifier – fixed effects; (B) conventional pacifier – fixed effects; and (C) had no habit – fixed effects.

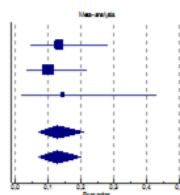
| A | Study                         | Sample size | Proportion (%) | 95% CI          |
|---|-------------------------------|-------------|----------------|-----------------|
|   | Adair et al, 1995             | 82          | 15,854         | 8,720 to 25,583 |
|   | Lima et al, 2016              | 50          | 6,000          | 1,255 to 16,548 |
|   | Zardeto et al, 2002           | 20          | 10,000         | 1,235 to 31,698 |
|   | <b>Total (fixed effects)</b>  | 152         | 12,197         | 7,495 to 18,409 |
|   | <b>Total (random effects)</b> | 152         | 11,815         | 6,212 to 18,912 |



#### Test for heterogeneity

|                                |               |
|--------------------------------|---------------|
| Q                              | 2,8711        |
| DF                             | 2             |
| Significance level             | P = 0,2380    |
| I <sup>2</sup> (inconsistency) | 30,34%        |
| 95% CI for I <sup>2</sup>      | 0,00 to 97,66 |

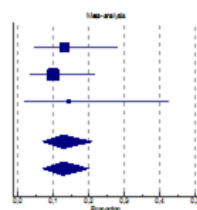
| B | Study                         | Sample size | Proportion (%) | 95% CI          |
|---|-------------------------------|-------------|----------------|-----------------|
|   | Adair et al, 1995             | 38          | 13,158         | 4,414 to 28,086 |
|   | Lima et al, 2016              | 50          | 10,000         | 3,328 to 21,814 |
|   | Zardeto et al, 2002           | 14          | 14,286         | 1,779 to 42,813 |
|   | <b>Total (fixed effects)</b>  | 102         | 12,744         | 7,035 to 20,668 |
|   | <b>Total (random effects)</b> | 102         | 12,744         | 7,084 to 19,763 |



#### Test for heterogeneity

|                                |               |
|--------------------------------|---------------|
| Q                              | 0,4256        |
| DF                             | 2             |
| Significance level             | P = 0,8083    |
| I <sup>2</sup> (inconsistency) | 0,00%         |
| 95% CI for I <sup>2</sup>      | 0,00 to 84,24 |

| C | Study                         | Sample size | Proportion (%) | 95% CI          |
|---|-------------------------------|-------------|----------------|-----------------|
|   | Adair et al, 1995             | 98          | 5,102          | 1,677 to 11,506 |
|   | Lima et al, 2016              | 101         | 0,990          | 0,0251 to 5,393 |
|   | Zardeto et al, 2002           | 27          | 0,000          | 0,000 to 12,770 |
|   | <b>Total (fixed effects)</b>  | 226         | 2,788          | 1,070 to 5,840  |
|   | <b>Total (random effects)</b> | 226         | 2,640          | 0,535 to 6,276  |



#### Test for heterogeneity

|                                |               |
|--------------------------------|---------------|
| Q                              | 3,4664        |
| DF                             | 2             |
| Significance level             | P = 0,1767    |
| I <sup>2</sup> (inconsistency) | 42,30%        |
| 95% CI for I <sup>2</sup>      | 0,00 to 82,56 |



## 5 CONCLUSÃO

Com base em evidências limitadas, parece haver uma maior prevalência de overjet acentuado e mordida aberta anterior em crianças com chupeta convencional em comparação com chupetas ortodônticas. No entanto, não há diferença na mordida cruzada posterior.

Parece que o tempo de uso em meses e horas por dia de chupeta está mais relacionado à má oclusão que a anatomia da chupeta propriamente.

Existe uma maior prevalência de má oclusão entre os usuários de chupetas ortodônticas e convencionais do que crianças sem o hábito





## **6 CONSIDERAÇÕES FINAIS**

Os estudos que comparam os dois tipos de chupetas apresentam limitações, pois é um tipo de estudo de difícil controle, seja pela falha na retrospectiva dos pais ou variáveis como padrão facial da criança que pode ser um fator de confusão. Apesar das controvérsias, o uso de chupetas traz benefícios para o bebê. Portanto o comportamento radical contra a chupeta não é indicado perante aos pais no consultório odontológico. O ideal é conscientizá-los quanto ao seu uso racional, de forma que evite a má oclusão e traga os benefícios esperados. Ao se indicar um tipo de chupeta, pode-se optar pela ortodôntica, mas consciente que a anatomia das chupetas não são o determinante para proteção da oclusão e sim o uso exacerbado em horas e meses de chupeta.



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## 8 ANEXO 1 - PRISMA Checklist e Protocolo, conforme registrado no PROSPERO.

| Section/topic                      | #  | Checklist item  |
|------------------------------------|----|---|
| <b>TITLE</b>                       |    |   |
| Title                              | 1  | Identify the report as a systematic review, meta-analysis, or both.   |
| <b>ABSTRACT</b>                    |    |   |
| Structured summary                 | 2  | Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria; participants; and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number. |
| <b>INTRODUCTION</b>                |    |   |
| Rationale                          | 3  | Describe the rationale for the review in the context of what is already known.  |
| Objectives                         | 4  | Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).  |
| <b>METHODS</b>                     |    |   |
| Protocol and registration          | 5  | Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.   |
| Eligibility criteria               | 6  | Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.  |
| Information sources                | 7  | Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.  |
| Search                             | 8  | Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.   |
| Study selection                    | 9  | State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).   |
| Data collection process            | 10 | Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.  |
| Data items                         | 11 | List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.   |
| Risk of bias in individual studies | 12 | Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.  |
| Summary measures                   | 13 | State the principal summary measures (e.g., risk ratio, difference in means).   |
| Synthesis of results               | 14 | Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., $I^2$ ) for each meta-analysis.   |

| Section/topic                 | #  | Checklist item   |
|-------------------------------|----|--|
| Risk of bias across studies   | 15 | Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).   |
| Additional analyses           | 16 | Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.   |
| <b>RESULTS</b>                |    |  |
| Study selection               | 17 | Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.  |
| Study characteristics         | 18 | For each study, present characteristics for which data were extracted (e.g., study size, PICO(S), follow-up period) and provide the citations.   |
| Risk of bias within studies   | 19 | Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).  |
| Results of individual studies | 20 | For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot. |
| Synthesis of results          | 21 | Present results of each meta-analysis done, including confidence intervals and measures of consistency.  |
| Risk of bias across studies   | 22 | Present results of any assessment of risk of bias across studies (see item 15).  |
| Additional analysis           | 23 | Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see item 16]).  |
| <b>DISCUSSION</b>             |    |  |
| Summary of evidence           | 24 | Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).                     |
| Limitations                   | 25 | Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).  |
| Conclusions                   | 26 | Provide a general interpretation of the results in the context of other evidence, and implications for future research.  |
| <b>FUNDING</b>                |    |  |
| Funding                       | 27 | Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.   |

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med doi:10.1371/journal.pmed1000097

For more information, visit [www.prisma-statement.org](http://www.prisma-statement.org).



## PROSPERO International prospective register of systematic reviews

### Review title and tiTmescale

#### 1 Review title

Give the working title of the review. This must be in English. Ideally it should state succinctly the interventions or exposures being reviewed and the associated health or social problem being addressed in the review.

**The use of orthodontic or conventional pacifier and malocclusion: a meta-analysis**

#### 2 Original language title

For reviews in languages other than English, this field should be used to enter the title in the language of the review. This will be displayed together with the English language title.

#### 3 Anticipated or actual start date

Give the date when the systematic review commenced, or is expected to commence.

**05/04/2016**

#### 4 Anticipated completion date

Give the date by which the review is expected to be completed.

**22/11/2016**

#### 5 Stage of review at time of this submission

Indicate the stage of progress of the review by ticking the relevant boxes. Reviews that have progressed beyond the point of completing data extraction at the time of initial registration are not eligible for inclusion in PROSPERO. This field should be updated when any amendments are made to a published record.

The review has not yet started **x**

| Review stage  | Started | Completed |
|---|---------|-----------|
| Preliminary searches  | No      | Yes       |
| Piloting of the study selection process                         | No      | Yes       |
| Formal screening of search results against eligibility criteria | Yes     | No        |
| Data extraction   | No      | No        |
| Risk of bias (quality) assessment                               | No      | No        |
| Data analysis   | No      | No        |

Provide any other relevant information about the stage of the review here.

### Review team details

#### 6 Named contact

The named contact acts as the guarantor for the accuracy of the information presented in the register record.

**Dr Ximenes**

#### 7 Named contact email

Enter the electronic mail address of the named contact.

**marcosximenes@outlook.com**

#### 8 Named contact address

Enter the full postal address for the named contact.

**Rua Manoel Severino de Oliveira, 185 Apt 106 zip code: 88062-120 City: Florianópolis State: Santa Catarina Brazil**

#### 9 Named contact phone number

Enter the telephone number for the named contact, including international dialing code.

**+55 48 9918 4787 +55 48 3209-5313**

#### 10 Organisational affiliation of the review

Full title of the organisational affiliations for this review, and website address if available. This field may be completed as 'None' if the review is not affiliated to any organisation.

**Federal University of Santa Catarina - UFSC**

Website address:

#### 11 Review team members and their organisational affiliations

Give the title, first name and last name of all members of the team working directly on the review. Give the organisational affiliations of each member of the review team.

| Title | First name | Last name | Affiliation                          |
|-------|------------|-----------|--------------------------------------|
| Dr    | Raphaela   | Medeiros  | Federal University of Santa Catarina |
| Dr    | Marcos     | Ximenes   | Federal University of Santa Catarina |
| Dr    | Carla      | Massignan | Federal University of Santa Catarina |

|    |            |               |                                      |
|----|------------|---------------|--------------------------------------|
| Dr | Carlos     | Flores-mir    | University of Alberta                |
| Dr | Ricardo    | Vieira        | Federal University of Santa Catarina |
| Dr | Andre Luis | Porporatti    | Federal University of Santa Catarina |
| Dr | Graziela   | De Luca Canto | Federal University of Santa Catarina |

## 12 Funding sources/sponsors

Give details of the individuals, organizations, groups or other legal entities who take responsibility for initiating, managing, sponsoring and/or financing the review. Any unique identification numbers assigned to the review by the individuals or bodies listed should be included.

None

## 13 Conflicts of interest

List any conditions that could lead to actual or perceived undue influence on judgements concerning the main topic investigated in the review.

Are there any actual or potential conflicts of interest?

None known

## 14 Collaborators

Give the name, affiliation and role of any individuals or organisations who are working on the review but who are not listed as review team members.

| Title | First name   | Last name | Organisation details                 |
|-------|--------------|-----------|--------------------------------------|
| Ms    | Maria Gorete | Savi      | Federal University of Santa Catarina |

## Review methods

### 15 Review question(s)

State the question(s) to be addressed / review objectives. Please complete a separate box for each question.

In infants and children, is there an association between the presence of malocclusion and the type of pacifier used (conventional or orthodontic)?

### 16 Searches

Give details of the sources to be searched, and any restrictions (e.g. language or publication period). The full search strategy is not required, but may be supplied as a link or attachment.

We will include observational studies in children who used orthodontic or conventional pacifiers aged 0 to 60 months who used orthodontic or conventional pacifier. All factors associated with pacifier use will be accepted. We will consider articles published and unpublished, in all languages, with no date restriction.

### 17 URL to search strategy

If you have one, give the link to your search strategy here. Alternatively you can e-mail this to PROSPERO and we will store and link to it.

I give permission for this file to be made publicly available

Yes

### 18 Condition or domain being studied

Give a short description of the disease, condition or healthcare domain being studied. This could include health and wellbeing outcomes.

Malocclusion

### 19 Participants/population

Give summary criteria for the participants or populations being studied by the review. The preferred format includes details of both inclusion and exclusion criteria.

Infants and children aged 0 to 60 months who used orthodontic or conventional pacifier

### 20 Intervention(s), exposure(s)

Give full and clear descriptions of the nature of the interventions or the exposures to be reviewed

Orthodontic pacifier

### 21 Comparator(s)/control

Where relevant, give details of the alternatives against which the main subject/topic of the review will be compared (e.g. another intervention or a non-exposed control group).

Conventional pacifier

### 22 Types of study to be included

Give details of the study designs to be included in the review. If there are no restrictions on the types of study design eligible for inclusion, this should be stated.

Malocclusion

### 23 Context

Give summary details of the setting and other relevant characteristics which help define the inclusion or exclusion criteria.

Inclusion criteria: We will include observational studies in children aged between 0 and 60 months who used orthodontic or conventional pacifiers. All factors associated with pacifier use will be accepted. We will consider published and unpublished articles, in all languages, with no date restriction. Exclusion criteria 1) studies in which sample includes children with genetic syndromic (e.g., Down syndrome, craniofacial anomalies, neuromuscular disorders, etc.); 2) studies in which sample includes children with presenting malignancies, malnutrition and chronic diseases; 3) children with other non-nutritional sucking habits, or lingual interposition, or enlarged adenoids, or respiratory problems; 4) in children with history of use of orthodontic appliances; 5) conducted in children over 60 months; 6) which the sample included maxillofacial surgery; 7) that did not measure pacifier use characteristics; 8) in children who used both models of pacifiers simultaneously (orthodontic and conventional) or not differentiate groups by types of pacifiers; (C - comparison) studies: 9) without an active control group (conventional pacifier); 10) duplicated references with the same sample; 11) Reviews, letters, personal opinions, case reports, book chapters and conference abstracts; and 12) articles not found.

#### 24 Primary outcome(s)

Give the most important outcomes.

Malocclusion

Give information on timing and effect measures, as appropriate.

#### 25 Secondary outcomes

List any additional outcomes that will be addressed. If there are no secondary outcomes enter None.

None

Give information on timing and effect measures, as appropriate.

None

#### 26 Data extraction (selection and coding)

Give the procedure for selecting studies for the review and extracting data, including the number of researchers involved and how discrepancies will be resolved. List the data to be extracted.

Will be done in two phases: 1. Two independent reviewers will read all abstracts and confront results. 2. Two reviewers will independently read the selected full articles and if there is disagreement, discuss which ones will be included. A third reviewer will be consulted in cases of discrepancies.

#### 27 Risk of bias (quality) assessment

State whether and how risk of bias will be assessed, how the quality of individual studies will be assessed, and whether and how this will influence the planned synthesis.

To assess the risk of bias of the studies the Joanna Briggs Institute MASTARI tool - Meta-analysis of Statistics Assessment and Review Instrument, for assessing risk of bias will be used

#### 28 Strategy for data synthesis

Give the planned general approach to be used, for example whether the data to be used will be aggregate or at the level of individual participants, and whether a quantitative or narrative (descriptive) synthesis is planned. Where appropriate a brief outline of analytic approach should be given.

The most relevant information will be grouped in Table 1 which will contain qualitative analysis of the information. If possible, meta-analysis is planned. If the meta-analysis is performed, the heterogeneity will be assessed using the I-squared.

#### 29 Analysis of subgroups or subsets

Give any planned exploration of subgroups or subsets within the review. 'None planned' is a valid response if no subgroup analyses are planned.

None planned

### Review general information

#### 30 Type and method of review

Select the type of review and the review method from the drop down list.

Epidemiologic, Systematic review

#### 31 Language

Select the language(s) in which the review is being written and will be made available, from the drop down list. Use the control key to select more than one language.

English

Will a summary/abstract be made available in English?

Yes

#### 32 Country

Select the country in which the review is being carried out from the drop down list. For multi-national collaborations select all the countries involved. Use the control key to select more than one country.

Brazil

#### 33 Other registration details

Give the name of any organisation where the systematic review title or protocol is registered together with any unique identification number assigned. If extracted data will be stored and made available

through a repository such as the Systematic Review Data Repository (SRDR), details and a link should be included here.

**34 Reference and/or URL for published protocol**

Give the citation for the published protocol, if there is one.

Give the link to the published protocol, if there is one. This may be to an external site or to a protocol deposited with CRD in pdf format.

I give permission for this file to be made publicly available

Yes

**35 Dissemination plans**

Give brief details of plans for communicating essential messages from the review to the appropriate audiences.

Do you intend to publish the review on completion?

Yes

**36 Keywords**

Give words or phrases that best describe the review. (One word per box, create a new box for each term)

Infant

Pacifier

Malocclusion

Systematic Review

**37 Details of any existing review of the same topic by the same authors**

Give details of earlier versions of the systematic review if an update of an existing review is being registered, including full bibliographic reference if possible.

**38 Current review status**

Review status should be updated when the review is completed and when it is published.

Ongoing

**39 Any additional information**

Provide any further information the review team consider relevant to the registration of the review.

**40 Details of final report/publication(s)**

This field should be left empty until details of the completed review are available.

Give the full citation for the final report or publication of the systematic review.

Give the URL where available.